

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

INTERVET, INC. and  
BTG INTERNATIONAL LIMITED,

Plaintiffs,

v.

MERIAL LIMITED,

Defendant.

Civil Action No. 05-887-KAJ

JURY TRIAL DEMANDED

**DEFENDANT MERIAL LIMITED'S  
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant Merial Limited ("Merial") as its Answer, Affirmative Defenses, and Counterclaim to each of the numbered paragraphs in the Amended Complaint of Plaintiffs Intervet Inc. and ("Intervet") and BTG International Limited ("BTG") (collectively "Plaintiffs"), responds and alleges as follows:

**Amended Complaint**

This unnumbered paragraph contains legal statements to which no answer is required.

**Parties**

1. Merial admits the allegations in paragraph 1.
2. Merial is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 and, therefore, denies the allegations.
3. Merial admits that it is a company limited by shares registered in England and Wales with a registered office in England, and domesticated in the state of Delaware as Merial LLC. Merial's North American Operational Headquarters is located in Duluth, GA.

**Jurisdiction and Venue**

4. Merial admits that the Amended Complaint purports to bring an action for patent infringement arising under the patent laws of the United States but denies that Intervet or BTG have any viable claim thereunder. Merial admits that this Court has jurisdiction over the subject matter of Plaintiffs' Amended Complaint but denies the legal sufficiency of Plaintiffs' claims and allegations.

5. Merial admits the allegations in paragraph 5.

6. Merial admits the allegations in paragraph 6.

**COUNT ONE- PATENT INFRINGEMENT**

7. Merial incorporates by reference its responses to paragraph 1 - 6 above as if fully repeated and restated herein.

8. Merial admits that what appears to be a true and correct copy of U.S. Patent No. 5,587,166 (the "'166 patent") was attached to the Amended Complaint at Exhibit A. Merial denies the remaining allegations in paragraph 8.

9. Merial admits that the title of the '166 patent is "Vaccine Against Pasteurella." Merial denies the remaining allegations in paragraph 9.

10. Merial admits that the '166 patent identifies British Technology Group Limited as assignee of the '166 patent. With respect to the remaining allegations in paragraph 10, Merial is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 10 and, therefore, denies the allegations.

11. Merial is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 11 and, therefore, denies the allegations.

12. Merial admits that it sells a vaccine against *Pasteurella* pneumonia. Merial admits that it sells RESPISHIELD®HM which is a vaccine against *Pasteurella* pneumonia.

Merial additionally admits that RESPISHIELD<sup>®</sup>HM can be acquired through its SUREHEALTH<sup>™</sup> program; but, also that other products for cattle can be acquired through its SUREHEALTH<sup>™</sup> program, as Merial's SUREHEALTH<sup>™</sup> program is a set of preconditioning protocols designed for, and to help, cow/calf veterinarians and producers improve the health, well being and performance of cattle. Merial denies the remaining allegations in paragraph 12.

13. Merial denies the allegations in paragraph 13.

14. Merial denies the allegations in paragraph 14.

15. Merial denies the allegations in paragraph 15.

16. Merial denies the allegations in paragraph 16.

#### **GENERAL DENIAL**

Except as specifically admitted herein, Merial denies each and every allegation contained in the Amended Complaint and denies that Plaintiffs are entitled to any of the relief requested in their prayer for relief.

#### **AFFIRMATIVE DEFENSES**

##### **First Affirmative Defense**

Merial's manufacture, use, sale, offer for sale, or importation of the accused products and/or methods does not infringe and has not infringed either directly, contributorily or by inducement any of the claims of the '166 patent.

##### **Second Affirmative Defense**

The '166 patent is invalid for failure to satisfy the requirement of 35 U.S.C. §§ 100, *et seq.*, including one or more of the following: 35 U.S.C. §§ 101, 102, 103, 112, 113, 119, 120, 121, 132, and 256.

**Third Affirmative Defense**

Intervet's and BTG's Amended Complaint fails to state a claim on which relief can be granted.

**Fourth Affirmative Defense**

Intervet's and BTG's claims are barred by the doctrine of unclean hands and/or patent misuse and/or unenforceability.

**Fifth Affirmative Defense**

Intervet's and BTG's claims are barred by the doctrine of equitable estoppel.

**Sixth Affirmative Defense**

Intervet's and BTG's prayer for injunctive relief is barred as against public policy.

**Seventh Affirmative Defense**

Intervet's and BTG's claims are barred by the doctrine of prosecution laches.

**Eighth Affirmative Defense**

Intervet's and BTG's claims are barred by prosecution history estoppel.

**Ninth Affirmative Defense**

Plaintiffs lack standing.

**COUNTERCLAIMS**

1. Counterclaim-Plaintiff Merial ("Merial"), for its Counterclaims for Patent Noninfringement, Invalidity, and Unenforceability against Counterclaim-Defendants Intervet, Inc. ("Intervet") and BTG International Limited ("BTG") alleges as follows:

**NATURE OF ACTION**

2. This is an action for declaratory judgment of noninfringement, invalidity, and unenforceability of United States Patent No. 5,587,166 (the "'166 patent").

**THE PARTIES, JURISDICTION AND VENUE**

3. Merial is a company limited by shares registered in England and Wales with a registered office in England, and domesticated in the state of Delaware as Merial LLC. Merial's North American Operational Headquarters is located in Duluth, Georgia.

4. On information and belief, Intervet is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 29160 Intervet Lane, Millsboro, Delaware.

5. On information and belief, BTG is a company registered in England with number 2664412 with its principal place of business at 10 Fleet Place, Limeburner Lane, London EC4M 7SB.

6. This counterclaim arises under the patent laws of the United States, Title 35, United States Code. Jurisdiction exists under 35 U.S.C. §§ 100, et seq., and 28 U.S.C. §§ 1331, 1338, 1367(a), 2201, and 220228 U.S.C. § 1331 and 1338(a).

7. Venue is proper in this judicial District under 28 U.S.C. §§ 1391 and 1400.

**COUNT 1**

**Declaration of Noninfringement**

8. Merial incorporates by reference the allegations of paragraphs 1-7 of its Counterclaims, as if fully set forth herein.

9. By filing this action, Intervet and BTG have created an actual controversy between the parties as to whether Merial's accused products and/or methods infringe any claim in the '166 patent.

10. Merial has not infringed, contributed to, or induced the infringement of, any claim of the '166 patent.

11. Merial is entitled to a declaratory judgment that the manufacture, use, sale, offer for sale, sale, or importation of their accused products and/or methods for making or using such do not infringe any claim of the '166 patent, either literally or under the doctrine of equivalents.

## **COUNT II**

### **Declaration of Invalidity**

12. Merial incorporates by reference the allegations of paragraphs 1-7, of its counterclaims, as if fully set forth herein.

13. By filing this action Intervet and BTG have created an actual controversy between the parties as to whether any of the claims of the '166 patent are valid.

14. The '166 patent is invalid for failure to satisfy the requirements of 35 U.S.C. §§ 100, *et seq.*, including one or more of the following: 35 U.S.C. §§ 101, 102, 103, 112, 113, 119, 120, 121, 132, and 256.

15. Merial is entitled to a declaratory judgment that the '166 patent is invalid.

## **COUNT III**

### **Declaration of Unenforceability**

16. Merial incorporates by reference the allegations of paragraphs 1-7 of its counterclaims, as if fully set forth herein.

17. The '166 patent issued December 24, 1996. Thus, the application from which the '166 patent issued was pending before the USPTO until that issue date. The '166 Patent corresponds to European Patent No. 0 287 206 and European Patent Application No. 88301932.5.

18. Akzo Pharma B.V. ("Akzo Pharma") lodged an Opposition against European Patent No. 0 287 206 and European Patent Application No. 88301932.5 on or about April 5, 1994 ("the European Opposition").

19. On information and belief, Akzo Pharma was a wholly owned subsidiary of Akzo N.V. On information and belief in 1994 Akzo N.V. merged with Nobel Industries and became Akzo Nobel N.V. ("Akzo Nobel"). On information and belief Akzo Pharma thus became wholly owned by Akzo Nobel (Akzo Pharma and Akzo Nobel are referred to herein both collectively and individually as "Akzo"). On information and belief, Intervet is the US operating division of Intervet International, bv. On information and belief, Intervet International, bv is a Dutch corporation, having its principal place of business in Boxmeer, Netherlands. On information and belief, Intervet International, bv is a division of Akzo. On information and belief the parent corporation of Intervet is Akzo Nobel, Inc., a wholly owned subsidiary of Akzo. On information and belief, Intervet is wholly owned by Akzo.

20. Akzo vigorously prosecuted the European Opposition and asserted that the European Patent and application corresponding to the '166 patent were invalid in view of prior art, including by way of a December 4, 1995 letter to the European Patent Office ("the Akzo December 4, 1995 European Opposition letter"). Thus, on or about April 5, 1994, a company in privity with Intervet, *i e*, Akzo, lodged the European Opposition asserting that the European Patent and application corresponding to the '166 patent are invalid in view of prior art; and, thereafter, Akzo vigorously prosecuted the European Opposition and asserted that the European Patent and application corresponding to the '166 patent are invalid in view of prior art.

21. By a Communication of a Notice of Opposition dated July 6, 1994, and a July 14, 1994 Communication of Notices of Opposition (Rule 57(1) EPC), the European Patent Office notified British Technology Group Limited, the named assignee of the '166 patent of the European Opposition. By a letter of July 26, 1994, British Technology Group Limited acknowledged receipt of the European Opposition, including prior art cited therein. By an

August 10, 1994 letter, the European Patent Office answered British Technology Group Limited's July 26, 1994 letter, advising that the European Opposition was admissible. On information and belief, the Akzo December 4, 1995 European Opposition letter was transmitted to and received by British Technology Group Limited prior to the issuance of the '166 patent. Thus, the European Opposition, the prior art cited therein, and the Akzo December 4, 1995 European Opposition letter were known to British Technology Group Limited, the named assignee of the '166 patent, prior to the issuance of the '166 patent.

22. None of Intervet, BTG, and British Technology Group Limited called the European Opposition, all of the prior art cited therein, or the Akzo December 4, 1995 European Opposition letter to the attention of the US Patent and Trademark Office ("USPTO") during the prosecution of the '166 patent.

23. On information and belief, the USPTO would have found the European Opposition to be material information to the patentability of the '166 patent claims.

24. On information and belief, the USPTO would have found the prior art cited in the European Opposition that was not cited to the USPTO to be material information to the patentability of the '166 patent claims.

25. On information and belief, the USPTO would have found the Akzo December 4, 1995 European Opposition letter to be material to the patentability of the '166 patent claims.

26. The European Opposition, the prior art cited therein but not cited to the USPTO, and the Akzo December 4, 1995 European Opposition letter refute and/or are inconsistent with positions the applicant took during the prosecution of the '166 patent.

27. On March 8, 2006, Merial filed at the USPTO a Request for Reexamination of the '166 patent.



28. On April 5, 2006, the USPTO ordered Reexamination of the '166 patent, citing thirteen prior art documents and finding eleven substantial new questions of patentability. Re-examination was ordered, in part, based on art cited in the European Opposition and rationale similar to that in the European Opposition and the Akzo December 4, 1995 European Opposition letter.

29. By filing this action, Intervet and BTG have created an actual controversy between the parties as to whether any of the claims of the '166 patent are enforceable.

30. Each individual associated with the filing and prosecution of a US patent application has a duty of candor and good faith in dealing with the USPTO. 37 CFR §1.56. At least British Technology Group Limited had that duty of candor and good faith during the prosecution of the '166 patent.

31. Individuals or entities that had the duty of candor and good faith during the prosecution of the '166 patent withheld material information from the USPTO during prosecution of the '166 patent. On information and belief, the applicant and/or the applicant's named assignee British Technology Group Limited intentionally and inequitably concealed from the USPTO material information, including the European Opposition and documents cited therein and the Akzo December 4, 1995 European Opposition letter and the arguments of Akzo therein, with an intent to deceive the USPTO.

32. The '166 patent is unenforceable due to inequitable conduct by the applicant and/or the named assignee British Technology Group Limited before the USPTO and/or the applicant's and/or the named assignee British Technology Group Limited's failure to comply with the duty of candor and good faith.

33. Merial is entitled to a declaratory judgment that the '166 patent is unenforceable

**PRAYER FOR RELIEF**

**WHEREFORE**, Merial prays that the Court:

(a) Declare that Merial's accused products and methods, including without limitation Merial's RESPISHIELD<sup>®</sup>HM product, and its entire SUREHEALTH<sup>™</sup> program and the methods of making and using Merial's RESPISHIELD<sup>®</sup>HM product, do not infringe the '166 patent;

(b) Declare that the '166 patent is invalid;

(c) Declare that the '166 patent is unenforceable;

(d) Declare that this to be an exceptional case pursuant to 35 U.S.C. § 285;

(e) Award Merial its attorneys' fees, costs and expenses in this action; and

(f) Award Merial such other and further relief as the Court deems just and proper.

**JURY TRIAL DEMAND**

Merial demands a trial by jury of all issues so triable in this action.


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Dated: June 2, 2006

  
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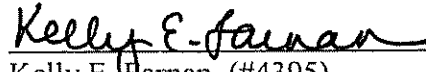
**CERTIFICATE OF SERVICE**

I hereby certify that on June 2, 2006, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filings, and hand delivered, to the following:

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I hereby certify that on June 2, 2006 I sent the foregoing document by Electronic Mail and Federal Express, next business day delivery, to the following non-registered participants:

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